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9-500

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**R. Michael McGrady, et al.**	)
		) Art Unit: **3651**
Serial No.:	**09/014,076**	)
		) Patent Examiner:
Filed:	**January 27, 1998**	) **Michael E. Butler**
		)
For:	**Method of Tracking and**	)
	Dispensing Medical Items	)

Commissioner of Patents and Trademarks
Washington, D.C.   20231

DECLARATION UNDER 37 CFR § 1.131

Sir:

I, R. Michael McGrady, hereby declare as follows:

1.   I am the Director of Engineering for the MedSelect Systems Division of Diebold, Incorporated ("Diebold"), the assignee of the above-identified patent application ("Application") and I am authorized on behalf of Diebold to provide this Declaration.

2.   I am an Applicant in the Application and am a joint inventor of the subject matter described in claims 38-53 thereof.

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3.   I have personal knowledge of all matters set forth in this Declaration.

4.   At all times mentioned herein I have been an employee of Diebold or its

predecessor entity, MedSelect Systems, Inc., which has now merged into Diebold, Incorporated.

5.   Prior to March 7, 1994 I had completed my invention as described and claimed in

the Application in at least claims 38 and 48 in this country as evidenced by the following:

a)   Prior to March 7, 1994, having previously conceived of the idea of a

system and method for tracking and dispensing medical items, I produced the

SelecTrac Functional Specification (Software) document ("Specification"), the

pertinent portions of which are attached hereto as Exhibit A;

b)   Prior to March 7, 1994, at the facilities of MedSelect Systems, Inc. located

in Cranberry Township, Pennsylvania (now a facility of Diebold, the Assignee of

the Application), I assembled a system for tracking and dispensing medical items

as described in the Specification, and successfully tested its method of operation

in a manner that proved that the system worked for its intended purposes.

This system included a database server computer which was a PC running

a type 486 processor. The computer had an associated data store running a

Paradox™ relational database management system like that described in the

Specification at pages 90 and 109.

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The relational database included data corresponding to a plurality of authorized users. I input this data to the system using an Administrator's Workstation which was a 486 PC running Paradox™ for Windows® and which had a monitor, keyboard and mouse connected thereto. The data for authorized users was input in response to displays provided by a graphical user interface software program I developed having a menu structure like that shown on page 60 of the Specification. The data records concerning authorized users were populated through the Administrator's Workstation by filling in the blanks on electronic input forms like that shown on page 65 of the Specification.

The database in the database server was also programmed with data corresponding to a plurality of types of medical items, and a plurality of storage locations in which the types of medical items were stored. I accomplished this by selecting storage locations for medical items in the medical item providing devices that were connected in the system. These storage locations included locations in hook registers, box registers, electronic lock cabinet (ELC) drawers and a medical item dispenser. After selecting the storage locations for each of a plurality of types of medical items, I input to the data store information on each medical item and its associated storage location. This was done using the Administrator's Workstation running the software with the menu structure described at page 60 of the Specification, and by populating the electronic input forms for assigning medical items to storage locations shown on page 64 of the Specification.

I also included in the database, data corresponding to identifying data for each of a plurality of patients. The patient data corresponded to names of persons, and information that would correspond to such persons if they were patients receiving medications in a hospital environment. Realistic medical data was included by myself for each corresponding patient. The patient data was input through the Administrator's Workstation, and the data was input by populating an electronic form for each patient of the type shown on page 62 of the Specification.

c)   Prior to March 7, 1994 I assembled, tested and successfully operated my system which included a display terminal. The display terminal was like that described on pages 74 and 111 of the Specification. The display terminal included an 80386 CPU with a flat touch screen monitor. The display terminal also had attached to it a magnetic stripe type card reader which was used to read data encoded on the magnetic stripe of cards. The card reader and touch screen served as input devices for inputting data for purposes of receiving user identifying data, selecting specific patients and for dispensing particular medical item types from the system.

The system that I made, tested and successfully operated prior to March 7, 1994 further included a number of medical item providing devices. These devices provided storage of medical items in storage locations from which the medical items were removable. These medical item providing devices included a dispenser from which selected medical items could be dispensed in response to electrical signals. This dispenser was like that described in the Specification on

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pages 7, 89-90 and 110. The dispenser was also like the dispenser (100) described in the Application.

Other medical item providing devices in my system included hook registers like those described in the Specification on pages 7, 89-90 and 109. The hook registers that I used were also like hook registers (10) described in the Application as well as in Diebold's prior Patent Application 08/009,055 filed January 25, 1993 (now U.S. Patent No. 5,404,384).

Other medical item providing devices connected in my system included box registers. These box registers were used for holding and detecting the removal of medical items held in boxes, and were like those described in the Specification on pages 7, 89-90 and 109. The box registers I used were also like box registers (110) described in the Application and in Diebold's prior Patent Application 08/186,285 filed January 25, 1994 (now U.S. Patent No. 5,533,089).

Another medical item providing device that was included in my system that was made, tested and successfully operated prior to March 7, 1994, was an electronic lock drawer unit which was alternatively referred to as an electronic lock cabinet (ELC). This electronic lock drawer unit included drawers with storage locations for medical items. The drawers were selectively unlocked by electrical signals. The electronic lock drawer unit I used was like that described in the Specification on pages 7 and 14. The electronic lock drawer unit was also like electronic lock drawer (92) described in the Application.

Each of the medical item providing devices in my system included at least one storage location for holding a type of medical item. I placed one type of medical item in each storage location corresponding to the data that I had input to the database for that storage location using the Administrator's Workstation. Only one type of medical item was placed in each storage location to assure that when a medical item was removed from that location, the proper type medical item corresponding to the data in the data store was received.

In my system which I made, operated and successfully tested prior to March 7, 1994, the medication dispenser was stocked with types of medical items which were containers holding solid and liquid medications including hypodermic solutions. Each type of medical item placed in the dispenser was positioned in a particular magazine. Each magazine served as a storage location in the dispenser from which the particular type of medical item could be dispensed. The magazine held the cylindrical containers housing the medical items to be dispensed. The containers were dispensed one at a time from the magazine in the manner described in the Application in connection with the operation of the dispenser (100). The medicine dispenser and magazines like those I used are also discussed in the Specification at page 110.

The hook registers used in my system each had a storage location which included a rod which supported medical items that were hung from the rod. In my system the particular types of medical items placed in the hook register storage locations were catheters as described in the Specification at page 109. The box

registers in my system each had a storage location holding a medical item. In my system the box registers each held a box containing a type of catheter in a manner like that described in the Specification at page 109.

In the system that I made, tested and successfully operated prior to March 7, 1994, the electronic lock drawer unit (also referred to as an ELC drawer) included a plurality of lockable drawers, each having compartments therein. In each compartment I had placed a different type of medical item. The medical items could be accessed only when the drawer having the storage location was unlocked, which occurred in response to signals sent to the lock controlling access to the particular drawer from the display terminal. This was done in a manner like that discussed in the Specification on pages 12 and 14.

The hook registers, box registers, electronic lock drawer unit and medication dispenser in my system were all connected by wiring connections to the display terminal. The display terminal was connected to the database server computer. The Administrator's Workstation, through which the data about users, patients, medications, storage locations and other information was input to the database, was also connected to the database server computer. As a result each of these components was operatively connected in a system network as described in the Specification at pages 89-90 and 109.

As previously discussed in the system that I made, tested and successfully operated prior to March 7, 1994, the database server was programmed by myself. I did this through inputs through the Administrator's Workstation so that the

database included data representative of each of the storage locations in the medical item providing devices, and the particular type of medical item that I had placed in each storage location. I provided inputs to record this information in the data store in a manner like that described on pages 60 and 64 of the Specification. The database server was further programmed by myself through inputs to the Administrator's Workstation to include in the data store, data representative of a plurality of patients for whom the medical items could be taken from the system. This was done in a manner like that described on pages 60 and 62 of the Specification.

d)   After the database server had been programmed and the medical items placed in the storage locations as already described, the system was successfully operated prior to March 7, 1994 to track and dispense medical items. In the operation of my system, I input data identifying myself to indicate to the system that I wanted to use the system to dispense medical items. The information I input to identify myself as a user, was received by the system through a data entry device. This was done by myself inputting a user ID number and a secret PIN number through the touch screen on the display terminal. Another way in which I input identifying data was to input my ID number by having it magnetically encoded on a magnetic stripe of a plastic card. The system read the stripe on the card as I passed the card through the card reader attached to the display terminal. I then input my secret PIN number through touch inputs to the touch screen. This was done in a manner like that described on pages 70 and 74 of the Specification.

Both methods of receiving identifying data corresponding to a user, successfully worked to have the system receive the data.

Once the identifying data was input, the processor in the database server computer operated to determine whether the user identifying data that I had input corresponded to stored data for an authorized user that I had previously stored in the data store. When the data I input did not correspond to stored data for an authorized user, the screen of the display terminal displayed a "logon failed" message. When the input data corresponded to the data stored in the data store for an authorized user, I was given further options to operate the system through the screen of the display terminal. The operation of my system in response to receipt of identifying data from authorized and unauthorized users was like that described in the Specification at pages 70 and 74.

Patient identifying data was then input through a data entry device. I did this through the touch screen on the display terminal of the system. The patient identifying data was input by highlighting the name of a selected patient, which I did by touching the selected patient name where it appeared on a list of patients displayed on the touch screen of the display terminal. The patient identifying data input corresponded to a patient for whom patient data had been previously stored in the database by myself. The input of patient identifying data to select a patient from the system was done by me in the manner described on pages 74 and 75 of the Specification.

Once the selected patient data was input, I then operated the system so that one unit of a type of medical item was removed from a storage location with a dispenser mechanism. This was done by myself touching the touch screen of the display terminal to highlight a particular type medical item that was displayed on the touch screen display. Once the selected type medical item was highlighted, the selected type medical item was dispensed in response to me touching a "dispense" button displayed on the touch screen. When the selected type medical item was held in the dispenser, which in my system was like dispenser (100) described in the Application, touching the "dispense" button removed one unit of the selected type medical item from the dispenser. This was accomplished by the display terminal sending a signal to the dispenser. The signal caused the magazine holding the type medical item I had selected to dispense one unit of that type medical item from the dispenser. I also operated my system so that when the type medical item I selected for dispense was held in a drawer of the electronic lock cabinet, signals were sent from the display terminal to unlock the drawer including the storage location with the selected type medical item. I then removed one unit of the type medical item from the storage location manually. The process by which I conducted these activities was like that described in the Specification on pages 76 and 77.

In the operation of my system, after I had "signed on" the system using data for an authorized user, selected a patient and a medical item, and had removed the selected type medical item from the storage location, the database

server computer operated using its processor to modify the data in the data store. The data was modified to include data which represented the dispense of the selected type medical item held in the storage location from which the medical item had been removed. The data was also modified through operation of the processor in the database server computer to include data representing that the type medical item had been taken for the selected patient. The way my system worked was like that described in the Specification at page 11, which describes that when a medical item is removed after a patient has been selected at the display terminal, the item removed from inventory is assigned to that selected patient.

After the database server computer operated to include the data in the data store, the successful operation of the system in tracking such data was demonstrated by myself generating a "patient usage" form for the patient I had selected on the display terminal. The patient usage form the system produced in response to my inputs was like that shown on page 79 of the Specification. The patient usage form showed that the particular type medical item had been taken for the selected patient. The operation of the processor in the database server to include in the data store the removal of the selected type medical item for the selected patient, was also shown by myself generating a usage report for the selected patient through inputs to the Administrator's Workstation. This was done in a manner like that described at page 83 of the Specification. The usage report

for the patient which I generated, showed that a record of the removal of the

selected type medical item for the selected patient was present in the data store.

e) In the system that I made, tested and successfully operated prior to

March 7, 1994 the processor in the database server computer also operated to

include in the data store, data representative that the authorized user for whom

identifying data had been input, had dispensed the particular type of medical item.

This was shown to have been accomplished successfully by myself producing

reports at the Administrator's Workstation. I produced a "usage report by patient"

form at the Administrator's Workstation for the patient I had selected and the form

showed that the user identification I had used, designated on the report as the

"system operator", was associated with the particular type medical item I

dispensed for the selected patient. This report was generated by myself through

inputs to the Administrator's Workstation, and the report was like that described at

page 83 of the Specification.

f) The system that I made, tested and successfully operated prior to March 7,

1994 had the database server computer further programmed by myself to require

that for certain types of medical items, before such items could be removed from

their respective storage locations, the system had to receive inputs of identifying

data from two authorized users. The types of medical items for which I required

inputs corresponding to two authorized users were certain types of medical items

which I had placed in storage locations in the medication dispenser. To remove

these medical items, I input identifying data corresponding to a first authorized

user through the display terminal in a manner like I have already discussed. When I requested to dispense one of these items, the system through the screen of the display terminal output a message that the system required input of user identifying data from a second authorized user which corresponded to data stored in the data store, before that type medical item would be dispensed. After data for a second authorized user was input by myself, the system allowed the selected type of medical item to be removed from the dispenser. I operated the system so as to input for these particular types of medical items, identifying data corresponding to both a first and a second authorized user. This was done by inputting a user ID number and PIN number for a first authorized user and then a user ID and PIN number for a second authorized user for which data had been stored in the data store. The system operated in a manner like that described on pages 76 and 77 of the Specification.

g)   The activities and method steps I have described herein were carried out by me personally or through operation of the described system components in response to my inputs, prior to March 7, 1994. These activities and method steps were carried out successfully and established that the system and method worked for its intended purposes.
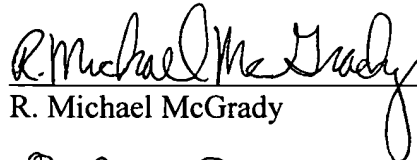
6.   As can be appreciated from the description of my activities, and as described in the Specification, the invention claimed in the Application was completed by being conceived and reduced to practice in this country prior to March 7, 1994. In addition and/or in the

alternative, the system which I have described herein, which is discussed in the Specification and which was completed by being conceived and reduced to practice in this country prior to March 7, 1994, renders the invention as claimed in the Application obvious to one having ordinary skill in the art. Each of the dates that have been deleted from the Specification is a date prior to March 7, 1994.

7.   The invention which is described as claimed in the Application was not in public use or on sale more than one year before December 16, 1994, the filing date of U.S. Patent Application Serial Number 08/367,783 from which the Application claims priority as a divisional pursuant to 35 U.S.C. § 120.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that such statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of the Application or any patent issuing thereon.

Respectfully submitted,

R. Michael McGrady

8-22-00
Date

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